

MAR 20 2006

**510(k) SUMMARY**  
**ASCLEPION LASER TECHNOLOGIES GmbH**  
**MeDioStar miXT Laser System**

K060455

This 510(k) summary of safety and effectiveness for the Asclepion Laser Technologies GmbH MultiStar Laser System is submitted in accordance with the requirements of 21 CFR 907.92 and follows Office of Device Evaluation Guidance concerning the organization and content of a 510(k) summary.

**Applicant:** ASCLEPION LASER TECHNOLOGIES GmbH  
Goeschwitzer Str. 51-52  
07745 Jena, Germany

**Contact Person:** Mr Reinhard Thieme  
Quality Assurance and  
International Regulatory Affairs

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**e-mail:** reinhard.thieme@asclepion.com

**Preparation Date:** January 31<sup>st</sup>, 2006

**Device Name:** MultiStar

**Common Name:** MultiStar

**Classification Name:** Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.481

**Equivalent Device:** Multipulse

**Device Description:** The MultiStar Laser System is a CO<sub>2</sub> - Gas Laser. It emits a beam of coherent light at the wavelength of 10600 nm with a maximum power of 30 Watt

**Intended Use:** The MultiStar is intended for coagulation, ablation, vaporization, incision, excision, cutting of soft tissue in plastic surgery, general surgery, oral surgery, ENT, gynecology and dermatology.

**Comparison to:** The MultiStar Laser System is substantially equivalent to the Multipulse Laser System, with the same principles of operation, the same wavelength and essentially the same power range as the predicate device for the same indications for uses.

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Nonclinical Performance Data: None

Clinical Performance Data: None

Conclusion: The MultiStar Laser System is another safe and effective device for coagulation, ablation, vaporization, incision, excision, cutting of soft tissue in plastic surgery, general surgery, oral surgery, ENT, gynecology and dermatology.

Additional Information : None



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 20 2006

Asclepion Laser Technologies GmbH  
c/o Mr. Reinhard Thieme  
Goeschwitzerstrasse 51-52  
Jenna, Germany 07745

Re: K060455

Trade/Device Name: MultiStar Laser System

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: February 14, 2006

Received: February 22, 2006

Dear Mr. Thieme:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

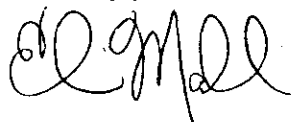
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Mark N. Melkerson  
Acting Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060455

Device Name: MultiStar Laser System

Indications for Use:

The MultiStar Laser System is intended for the coagulation, ablation, vaporization, incision, excision, cutting of soft tissue in plastic surgery, general surgery, oral surgery, ENT, gynecology and dermatology.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative  
and Neurological Devices**

510(k) Number K060455

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